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Mr. Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Road
Rockville, MD 20850
FAX # (301) 594-4672

Dear Mr. Spears:

It had recently come to my attention that the FDA has proposed a new policy regarding the regulation of reprocessors of single use medical devices. As a therapeutic endoscopist/gastroenterologist who trained using such devices, I do believe there is a potential role for such devices. However, I can also state based on my own experience, that such equipment has, on occasion, failed to perform, adding to procedure time and patient risk. As the Director of a busy endoscopy suite which specializes in complicated endoscopic procedures, I am also acutely aware of cost considerations which make the reuse of single use devices appealing. As the crux of the issue is the provision of safe and effective medical care to patients, I strongly support the FDA's efforts to increase regulation of reprocessors of such equipment. I do question whether the new policy is adequate to meet the goal of ensuring patient safety.

This is an area of obviously competing self interests of hospitals, manufacturers, and reprocessors in which much verbiage, but little factual data is available. I would have to concur with some that without such data, the reuse of disposable devices is akin to human experimentation without patient consent. I would encourage the FDA to take an aggressive, proactive approach to this issue. This would hold reprocessors to the same standards as those for reusable devices, while putting the onus on the reprocessors to conduct the clinical studies to document the safety and efficacy of the reprocessed devices. To do less would put patients at unnecessary risk. Leaving open the option of changing the regulation will provide financial incentive to collect the necessary data, which for some devices will demonstrate the safety and efficacy of reprocessing. This is not an issue to be rightly decided by the scribblings of journalists, the rantings of corporate attorneys, or the repetitive declarations of medical misadventures.

Sincerely yours,

Olch Haluszka, M.D.
Director, GI Endoscopy

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